

## **REMARKS**

### **I. Status of the Application**

Claims 1, 3-37, and 50-52 are presently pending in the application. Claims 2 and 38-49 have been previously cancelled. Applicant gratefully acknowledges the withdrawal of the 35 U.S.C. § 102(b) rejection of claim 13 as being anticipated by Scheicher (U.S. Patent No. 4,278,630), the withdrawal of the 35 U.S.C. § 102(b) rejection of claims 6-7 and 11-12 as being anticipated by WO 86/04088, the withdrawal of the 35 U.S.C. § 102(b) rejection of claims 13-14 as being anticipated by WO 98/47465, and the withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1, 3-6, 9-10, 15-26, 29-32, and 34-36 as being unpatentable over WO 86/04088. Claims 1, 3-5, 13-14, 17-18, 21-26, 29-30, and 34-36 stand newly rejected under 35 U.S.C. § 102(e) as being anticipated by Ylanen et al. (U.S. Patent No. 6,517, 857, hereinafter "Ylanen"). Claims 15-16, 19-20, and 29-30 stand newly rejected under 35 U.S.C. § 103(a) as being obvious over Ylanen. Claims 28 and 31 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant gratefully acknowledges the Examiner's indication that claims 6-12, 27, 32-33, 37, and 50-52 are allowed.

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. Specifically, Applicant has amended dependent claim 31, as suggested by the Examiner, into independent form including all of the limitations of base claim 1. Accordingly, no new matter is believed to have been added. Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

### **II. Interview Summary**

Applicant is grateful to the Examiner for extending the courtesy of a telephone interview with Applicant's representative on November 8, 2006. Applicant thanks the Examiner for indicating the allowance of claims 21, 22, 24, and 26, because the prior art does not provide for a sintered glass scaffold comprising glass fibers sintered together to form the scaffold, wherein the glass fibers have a coating of one or more biocompatible polymers or copolymers. Applicant also thanks the Examiner for indicating the allowance of claim 28 without further amendment,

because claim 28 is already in independent form. The Examiner also acknowledged errors in the Office Action at page 3, section 9 and page 4, section 11, which erroneously state that Ylanen has a common inventor with the present application.

### **III. Claims 1, 3-5, 13-14, 17-18, 21-26, 29-30, and 34-36 Are Novel over Ylanen**

At page 3, paragraph 9 of the instant Office Action, claims 1, 3-5, 13-14, 17-18, 21-26, 29-30, and 34-36 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Ylanen. Applicant again thanks the Examiner for indicating in the telephone interview of November 8, 2006 that claims 21, 22, 24, and 26 are allowed. The Examiner is of the opinion that sintering of the fibers is a process limitation that should not be given any patentable weight, and that the product of Ylanen is the same as the product of the instant application. Applicant respectfully traverses the rejection.

Contrary to the Examiner's opinion, the term "sintered" recited in the subject claims is not a process limitation. "Sintered" is an adjective that describes the structure and material properties of the scaffold. Chamber's Science and Technology Dictionary defines "sinter" as follows: "To coalesce into a single mass under the influence of heat, without actually liquefying." Thus, a sintered glass fiber scaffold is a single coalesced mass of fused glass fibers, in which the original fiber boundaries are no longer present (please see Attachments A and B; please also see the attached declaration of inventor Eija Pirhonen stating that the scanning electron microscope images shown in Attachments A and B are of a sintered glass fiber scaffold according to an embodiment of the claimed invention). The sintered scaffold has a defined, rigid, 3-dimensional structure with defined porosity and pore size (specification, page 7, lines 17-25). Because the sintered scaffold is a single fused mass, it has excellent load bearing properties, and can have sufficiently high compressive strength to carry loads (page 7, lines 34-36, page 10, lines 18-22). The properties of the sintered scaffold, such as its strength and structure, can be varied by varying the sintering temperature, sintering time, and the compressive load under which the scaffold is sintered, as recited in dependent claims 3-5, 17, 18, 29, 30, and 35.

In contrast, the "textile product" of Ylanen is not sintered, so it is not a single coalesced mass and its structure is flexible and compressible. The textile product is manufactured by drawing shorter or longer fibers from glass, and by spraying shorter fibers together to form a mat (column 4, lines 17-22). At this point, the textile product is just a mass of intertwining fibers

which are not fused to each other, so the fibers will disentangle if pulled, or slide together and compress if a load is applied. Ylanen further discloses that the textile product may be hardened by impregnating with a substance such as simulated body fluid or a collagen adhesive, and that impregnation creates an apatite junction at the intersections of the fibers (column 4, lines 23-29). However, the fibers of Ylanen's impregnated textile product are not fused together as seen in Attachments A and B, but maintain their individual fiber structures. The apatite junctions, being weak and brittle, merely lightly adhere the fibers at their contact points. The impregnated textile product of Ylanen is certainly not a single coalesced mass as is the sintered scaffold of the subject claims. Since its fibers are only lightly adhered by apatite junctions and not coalesced into a single mass, the impregnated textile product of Ylanen does not possess the compressive strength necessary to carry loads, but only possesses the strength to maintain its molded shape. Ylanen also fails to disclose any specific porosity for its textile product, much less a porosity of between about 50 volume % and about 90 volume %, as recited in independent claim 1.

For at least the foregoing reasons, the unsintered textile product of Ylanen is not the same product as the sintered scaffold of the subject claims. The sintered scaffold of the subject claims, which is a single coalesced mass, is structurally different from the unsintered textile product of Ylanen, which has fibers lightly adhered by apatite junctions. Because of its structural differences, the sintered scaffold recited in the subject claims also possesses different properties from the unsintered textile product of Ylanen. Therefore, Ylanen fails to teach or suggest each and every limitation of the subject claims, and so Ylanen fails to anticipate the subject claims. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(e) rejection and allowance of claims 1, 3-5, 13-14, 17-18, 23, 25, 29-30, and 34-36.

#### **IV. Claims 15-16, 19-20, and 29-30 Are Nonobvious over Ylanen**

At page 4, paragraph 11 of the instant Office Action, claims 15-16, 19-20, and 29-30 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ylanen. The Examiner is of the opinion that it would have been obvious to one of ordinary skill in the art to modify the teachings of Ylanen to arrive at the recited fiber lengths and fiber diameters in order to have a porous product that can be manufactured into a mat. Applicant respectfully traverses the rejection.

As submitted above in section III, Ylanen fails to disclose a sintered glass fiber scaffold. Nor does Ylanen disclose the porosity or compressive strength recited in the subject claims. The

sintered scaffold of the subject claims is a different product with different properties than Ylanan's unsintered textile product. The Examiner admits that Ylanan fails to disclose the length or diameter of the fibers. Ylanan also fails to disclose the compressive strength of its textile product. The Examiner is of the opinion that one of ordinary skill in the art would find it obvious to include fibers of the lengths and diameters recited in the subject claims in order to have a porous product that can be manufactured into a mat. However, the skilled artisan reading Ylanan would not be motivated to use fibers of the recited lengths and diameters in a sintered glass fiber scaffold. Ylanan in no way suggests the desirability of a sintered glass fiber scaffold, nor does Ylanan suggest suitable fiber lengths or diameters for such a sintered scaffold. In fact, Ylanan teaches that its (unsintered) textile product provides more rapid ossification than do prior art composites, such as sintered glass microspheres (column 1, line 34 to column 2, line 36), thus suggesting that a sintered scaffold is undesirable. In addition, even though the textile product of Ylanan may be hardened to retain a molded shape, Ylanan does not suggest that it can carry loads, so Ylanan provides no motivation to modify its teachings to produce a sintered scaffold having the compressive strength recited in claims 29 and 30.

For at least the foregoing reasons, claims 15-16, 19-20, and 29-30 are not obvious over Ylanan. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 15-16, 19-20, and 29-30.

#### **V. Objection to Claims 28 and 31**

At page 5, paragraph 12 of the instant Office Action, claims 28 and 31 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten into independent form. Applicant thanks the Examiner for agreeing that claim 28 is already in independent form, and for indicating that claim 28 is thus allowable without further amendment. Claim 31 has been amended into independent form including all of the limitations of the base claim, according to the Examiner's suggestion. Thus, claim 31 should be allowable. Accordingly, Applicant respectfully requests withdrawal of the objection and allowance of claims 28 and 31.

**VI. Conclusion**

Having addressed all outstanding issues, Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

The Commissioner is authorized to apply any charges or overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

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